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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/930,105	08/15/2001	Fred S. Lamb	17023.017US1	9991	
53137 7590 04/13/2007 VIKSNINS HARRIS & PADYS PLLP P.O. BOX 111098			EXAMINER		
			KIM, JENNIFER M		
ST. PAUL, MN 55111-1098			ART UNIT	PAPER NUMBER	
			1617		
		•	MAIL DATE	DELIVERY MODE	
			04/13/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	•
09/930,105	LAMB ET AL.	
Examiner	Art Unit	
Jennifer Kim	1617	

Before the Filling of all Appear Brief	Examiner	Art Unit						
	Jennifer Kim	1617						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address								
THE REPLY FILED 16 March 2007 FAILS TO PLACE THIS AF								
<ol> <li>The reply was filed after a final rejection, but prior to or or this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a Not a Request for Continued Examination (RCE) in complian- time periods:</li> </ol>	n the same day as filing a Notice of wing replies: (1) an amendment, aff otice of Appeal (with appeal fee) in o	Appeal. To avoid aba idavit, or other evider compliance with 37 C	nce, which FR 41.31; or (3)					
a) The period for reply expiresmonths from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In								
no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.								
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN								
TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed,								
may reduce any earned patent term adjustment. See 37 CFR 1.704(b NOTICE OF APPEAL	).		•					
<ol> <li>The Notice of Appeal was filed on 16 March 2007. A brief the date of filing the Notice of Appeal (37 CFR 41.37(a)), appeal. Since a Notice of Appeal has been filed, any replacement.</li> </ol>	or any extension thereof (37 CFR 4	41.37(e)), to avoid dis	missal of the					
<u>AMENDMENTS</u> 3.	but prior to the date of filing a brief	will not be entered b	ACSUSA					
<ol> <li>The proposed amendment(s) filed after a final rejection,</li> <li>(a) They raise new issues that would require further contains</li> </ol>			ecause					
(b) They raise the issue of new matter (see NOTE below		50.0,,	•					
(c) ☐ They are not deemed to place the application in be appeal; and/or		ducing or simplifying	the issues for					
(d) They present additional claims without canceling a		ected claims.	•					
NOTE: (See 37 CFR 1.116 and 41.33(a))								
4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  5. Applicant's reply has overcome the following rejection(s): See Continuation Sheet.								
<ol> <li>Newly proposed or amended claim(s) would be a non-allowable claim(s).</li> </ol>								
7.  For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is pro The status of the claim(s) is (or will be) as follows:	☐ will not be entered, or b) ☐ wi ovided below or appended.	Il be entered and an o	explanation of					
Claim(s) allowed: Claim(s) objected to:								
Claim(s) objected to: Claim(s) rejected: <u>22-24,27-29,31-35 and 38-43</u> .	·							
Claim(s) withdrawn from consideration:								
AFFIDAVIT OR OTHER EVIDENCE								
<ol> <li>The affidavit or other evidence filed after a final action, be because applicant failed to provide a showing of good ar was not earlier presented. See 37 CFR 1.116(e).</li> </ol>	ut before or on the date of filing a N nd sufficient reasons why the affidat	otice of Appeal will <u>no</u> vit or other evidence i	ot be entered s necessary and					
9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to showing a good and sufficient reasons why it is necessal	overcome all rejections under appe	al and/or appellant fa	ils to provide a					
10. The affidavit or other evidence is entered. An explanation								
REQUEST FOR RECONSIDERATION/OTHER								
<ol> <li>The request for reconsideration has been considered be <u>See Continuation Sheet.</u></li> </ol>		n condition for allowa	nce because:					
12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s).								
13.								
•								
			>					

U.S. Patent and Trademark Office PTOL-303 (Rev. 08-06) Jennifer Cim Patent Examinen Part of Paper No. 20070409

## **Continuation Sheet (PTO-303)**

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112, first paragraph, new matter rejection (claims 22-24, 27-36 and 38-43).

Continuation of 11. does NOT place the application in condition for allowance because: The claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. Applicants essentially argue that there is a lack of causation (i.e., a cause-and-effect relation) between the administration of tamoxifen and the effect observed by Delaney et al. because Delaney et al. do not show a correlation between the administration of tamoxifen to the patient and the observed increased in libido in the patient and that Delaney et al. do not anticipate claims 22-24 and 27-29, because Delaney et al. merely discloses that one male breast cancer patient on a tamoxifen regimen had experienced an increased libido during the course of treatment and that the period of time in which he had a increased libido was not co-extensive with the period of time in which he was administered tamoxifen. This is not found persuasive because Delaney et al. clearly teaches that the patient being treated by Delaney et al. had enhanced libido upon administration of tamoxifen is the indication that the patient had existing libido condition; and that when tamoxifen treatment was continued, the libido condition was returned to normal which indicates that tamoxifen normalized the libido condition during this time period of treatment. During this time of treatment clearly anticipates Applicants' claimed invention of treating erectile dysfunction as administration of tamoxifen to Delaney's patient enhanced libido condition. Applicants' recitation of modulating penile vascular tone by administration of tamoxifen is unavoidable mechanism during the treatment with same active agent administered to same population disclosed by Delaney et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.